



UNITED STATES PATENT AND TRADEMARK OFFICE

7.

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,759	09/12/2003	Andrea Liebmann-Vinson	P-5843	5974

46851 7590 08/09/2007
DAVID W. HIGHER, VP & CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

STOICA, ELLY GERALD

ART UNIT	PAPER NUMBER
----------	--------------

1647

MAIL DATE	DELIVERY MODE
-----------	---------------

08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/660,759	Applicant(s) LIEBMANN-VINSON ET AL.	
	Examiner Elly-Gerald Stoica	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claim 22 drawn to an invention nonelected without traverse in the reply filed on 10/24/2006. The claim has been withdrawn by the Examiner in the Office action sent on 02/01/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Maintained claims rejection

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-21 and 23-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Banes AJ (US Pat. 4,822,741, 04/18/1989) in view of Stitt et al. (US Pat 5,567,598, 10/22/1996), (both cited by the Applicant), for the reasons of record. At page 5, applicants argue: "... that the 4-amino acid oligopeptide used by Banes cannot be considered an "extracellular matrix molecule" (claim 27). Applicants point out that the sequence "RGDS" is not restricted to extracellular matrix proteins, but rather, it can be readily found in the amino acid sequences of many eukaryotic and prokaryotic intracellular proteins, such as human adenylate cyclase type IX and glycine

Art Unit: 1647

dehydrogenase from *Pseudomonas aeruginosa*. Although the Office Action alleges that Banes teaches "a peptide (RGDS) derived from the protein fibronectin, which is an extracellular matrix adhesion molecule", Applicants could find no teaching in Banes that the RGDS sequence is derived from either fibronectin, or indeed, from any extracellular matrix protein. "This argument has been fully considered but is not deemed persuasive because the motif RGDS is (and was, at the time that the invention was made) considered a quintessential motif for extracellular matrix molecules, as evidenced by one of the plethora of references regarding "RGDS": Grooms et al. (Neuroscience Letters, 231, 139-142, 1997) (abstract and p. 140, left col., lines 15-17). Banes did not have to specifically teach that the RGDS sequence is derived from an extracellular matrix molecule because that was an indisputable established scientific fact for a person of ordinary skill in the art. At page 6, applicants argue: "Applicants assert that one skilled in the art would not even try to combine the methods of Banes and Stitt to arrive at the claimed invention. Applicants assert that one skilled in the art would not look to Stitt to correct the deficiencies of Banes because the two references are from entirely different fields of research." This argument has been fully considered but is not deemed persuasive because, first, Banes teaches: "A polyorganosiloxane composition having a biocompatible surface thereon is disclosed. The biocompatible surface results from the derivatization, or amination, of the surface intended for cell contact. More specifically, the present invention is a polyorganosiloxane composition in which the surface is either treated with a primary amine and optional peptide or the surface is co-cured with a primary amine-containing silane or siloxane. The aminated polyorganosiloxane has utility as a cell culture substrate or in a

Art Unit: 1647

variety of artificial organ applications such as breast implants, synthetic blood vessels, joints, tendons and heart valves." (U.S. Pat. No. 4,822,741-abstract). Therefore, Banes teaches surfaces designed for cell culture. Applicant also argue that: "The specification in Banes therefore precludes the possibility of the Banes apparatus having microbial contamination" because Banes sterilized the plates. While acknowledging the sterilization of Banes, Applicant's attention is drawn that the sterilization technique is not fail safe and there are instances in which contamination might inadvertently occur.

A very convenient way to asses the viability of the cell in the cell culture would have been to combine the Banes teachings with the teachings of Stitt, because Stitt specifically states that: "it is an object of the invention to provide a means for detection and/or monitoring the activity of oxygen consuming enzymes or enzyme systems without the use of dedicated instrumentation." (U. S. Pat. No. 5, 567,598, col. 3 lines 35-39). Viable cells would constitute the oxygen consuming enzyme system and a person of ordinary skill in the art would have preferred to asses cell viability without dedicated instrumentation, if offered the opportunity. Therefore, It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have combined the teachings of Banes and Stitt et al., with guaranteed success.

Conclusion

4. No claims are allowed

Art Unit: 1647

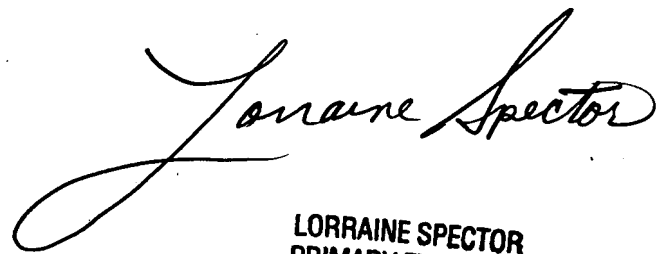
5. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR
PRIMARY EXAMINER